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REMARKS

This is a full and timely response to the non-final Official Action mailed April 22, 2005. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Claims 17-35 were withdrawn under a previous Restriction Requirement. To expedite the issuance of this application, claims 17-35 have been cancelled herein. The withdrawn claims are cancelled without prejudice or disclaimer. Applicant reserves the right to file any number of continuation or divisional applications to the cancelled claims or to any other subject matter described in the present application.

No amendments are made to original claims 1-16. No other claims are added or cancelled. Thus, claims 1-16 are currently pending for the Examiner's consideration.

Election/Restriction:

In an earlier Office Action, dated October 4, 2004, the Office required Applicant to elect one of the following claim groups for immediate prosecution: (1) claims 1-16, (2) claims 17-21, (3) claims 22-32 and (4) claims 33-35. Accordingly, in a response filed October 27, 2004, Applicant elected the first claim group, claims 1-16 for immediate prosecution. Consequently, claims 17-35 were withdrawn from consideration.

The Office then required a subsequent species election in a second Office Action dated January 13, 2005. As a result of Applicant's subsequent election, claims 6, 7 and 9-13 were also withdrawn from consideration as being directed to non-elected species.

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Applicant now notes that claims 6, 7 and 9-13 all depend ultimately from claim 1, and that no prior art rejection of claim 1 has been made. Claim 1 is generic to all the species enumerated in the Office Action of January 13, 2005, including the species represented by claims 6, 7 and 9-13.

Consequently, Applicant is now entitled to an examination of dependent claims 6, 7 and 9-13, which are clearly allowable over the prior art based on, at least, their dependence on claim 1. See MPEP § 806.04(d). Therefore, the reintroduction and examination of claims 6, 7 and 9-13 with allowable claim 1 is respectfully requested.

Double Patenting:

The sole issue raised against the pending claims in the outstanding Office Action is a rejection of claims 1-5, 8 and 14-16 as being an instance of double patenting under the judicially-created doctrine of obviousness-type double patenting in view of U.S. Patent No. 6,735,475 to Whitehurst, et al. ("the '475 patent") considered in light of U.S. Patent No. 5,330,515 to Rutecki, et al. ("Rutecki"). For at least the following reasons, Applicant respectfully traverses this rejection.

Claim 1 recites a method of stimulating the vagus nerve to treat a number of conditions. Pursuant to Applicant's earlier species election, the recent Office Action, in making the double patenting rejection, focuses exclusively on the treatment of headaches (Action of 4/22/05, p. 2).

Claim 1 recites:

A method for treating a patient with at least one of epilepsy, a metabolic disorder, a mood disorder, an anxiety disorder, chronic pain, a gastrointestinal disorder, hypertension, a cardiac disorder, a psychotic disorder, a cognitive disorder, dementia, an eating disorder, a sleep disorder, an endocrine disorder, a movement disorder, and *headache*, comprising:

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providing at least one leadless stimulator having at least two electrodes;

implanting the at least one stimulator adjacent to at least one portion of the vagus nerve;

providing operating power to the at least one stimulator;

using at least one external appliance to transmit stimulation parameters to the at least one stimulator;

receiving and storing the stimulation parameters;

generating stimulation pulses in accordance with the stimulation parameters; and

delivering the stimulation pulses to nerve fibers adjacent to the at least one stimulator;

wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one portion of the vagus nerve.
(emphasis added).

According to the recent Office Action, U.S. Patent No. 6,735,475 teaches a headache treatment, but “does [not] specify the vagus nerve as the location for treatment.” (Action of 4/22/05, p. 2). In fact, no prior art reference teaches or suggests stimulation of the vagus nerve as a potential treatment for headaches or facial pain.

The ‘475 patent does not teach or suggest, or even mention, stimulation of the vagus nerve. Consequently, the recent Office Action also cites Rutecki. According to the Office Action, the teachings of the ‘475 patent and Rutecki may be combined to render obvious the method of treating headaches recited in claim 1. Applicant respectfully disagrees.

According to the recent Office Action, Rutecki “is provided as evidence that given the claim of the ‘475 patent, the use of the device for [stimulating] a vagus nerve for treating pain would have been obvious.” (Action of 4/22/05, p. 2). Rutecki does teach stimulation of the vagus nerve. However, Rutecki does not teach or suggest a method of stimulating the vagus nerve to treat chronic headaches. Rather, Rutecki teaches stimulation of the vagus nerve to

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create a neural "block" to pain signals that are originating in the body below the site of stimulation. Rutecki expressly describes stimulating "the patient's cervical vagus nerve or other site preferably above the location of the pain to stimulate afferent fibers for activating a descending anti-nociceptive pathway and thereby blocking incoming pain signals." (Rutecki, abstract).

The inquiry for obviousness under double patenting parallels the question of obviousness under 35 U.S.C. § 103. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Thus, the question is whether the combination of the '475 patent with the Rutecki would have led of ordinary skill in the art to the claimed method of stimulating the vagus nerve to treat headaches. If the proposed combination of prior art teaches does not suggest to one of skill in the art all the features of the claimed invention, obviousness cannot be established. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03.

In the present case, neither of the prior art references teach or suggest that stimulation of the vagus nerve will be effective to treat a headache as recited in claim 1. The method of stimulating the vagus nerve to treat a headache comes exclusively from Applicant's specification.

As noted, the '475 patent claims a treatment for headache and/or facial pain, e.g., pain in the patient's head, but does not teach or suggest that the vagus nerve may be stimulated to achieve that effect. The only reference of record that teaches any stimulation of the vagus nerve, Rutecki, teaches that the stimulation is performed, not to treat a headache, but to treat pain below the site of stimulation. Consequently, one of skill in the art, reading of the "descending anti-nociceptive pathway" of Rutecki to treat pain located below the stimulation site, i.e., below, or inferior to, the cervical vagus nerve, would not think it obvious to

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stimulate the vagus nerve as part of the method of the '475 patent for treating headaches and/or facial pain, because this pain originates above, or superior to, the cervical vagus nerve.

Consequently, even if combined, the '475 patent and Rutecki would not reasonably suggest or one of skill in the art the claimed method in which the vagus nerve is stimulated to effectively treat a headache. Therefore, the claims of the present application are not merely an "obvious variation of the invention defined in a claim in the ['475] patent." *See* MPEP § 804. Therefore, the double patenting rejection should be reconsidered and withdrawn.


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Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper which have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,



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DATE: 15 July 2005

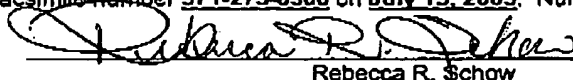
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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number 571-273-8300 on July 15, 2005. Number of Pages: 15


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